

REMARKS

I. Status of the Claims

Claims 1-88 were originally filed. Claims 6, 20-69, 71, 76-82, and 84 have been canceled. Claims 1-5, 7-19, 70, 72-75, 83, and 85-88 are pending under examination.

Upon entry of the present amendment, claim 5 is amended to recite "wherein the amino acid at position 577 has been substituted by a different amino acid." This amendment does not introduce new matter, since position 577 in SEQ ID NO:20 corresponds to position 208 in SEQ ID NO:2 and position 183 in SEQ ID NO:4 (see Exhibit 1). Claim 13 is amended to add the missing space between "of" and "MTB8.4." Claim 83 is amended to recite an "isolated fusion polypeptide" instead of an "isolated polypeptide encoding a fusion polypeptide." This amendment merely corrects a grammatical error and introduces no new matter.

III. Claim Rejections

A. Double Patenting

Claims 1, 4, 5, and 19 were rejected under the judicially created doctrine of obviousness-type of double patenting over claim 1 of U.S. Patent No. 6,627,198. Applicants respectfully traverse the rejection in light of the present amendment.

Claim 1 of U.S. Patent No. 6,627,198 ("the '198 patent") is drawn to a purified polypeptide comprising the amino acid sequence of SEQ ID NO:26, which is identical to SEQ ID NO:20 of the present application. Following the amendment of November 22, 2004, claim 1 recites "at least one amino acid corresponding to position 183 of SEQ ID NO:4 or position 208 of SEQ ID NO:2 in the MTB32A antigen (SEQ ID NO:2 or 4) has been substituted by a different amino acid." As indicated in Exhibit 1, it is clear that SEQ ID NO:20 of the present invention (or SEQ ID NO:26 of the '198 patent) contains a partial sequence of SEQ ID NO:2 or SEQ ID NO:4, including position 208 of SEQ ID NO:2 or position 183 of SEQ ID NO:4, which is a serine and corresponds to position 577 in SEQ ID NO:20. Thus, the limitation that at least one of these two positions is substituted with a different amino acid requires claim 1 to exclude SEQ

ID NO:20, when position 577 remains a serine. For this reason, claims 1, 4, and 19 are not obvious over claim 1 of the '198 patent.

Upon entry of the present amendment, claim 5 is further amended to recite "wherein the amino acid at position 577 has been substituted by a different amino acid." This newly added limitation explicitly distinguishes the fusion polypeptide in the claimed composition from SEQ ID NO:26 of the '198 patent. Thus, the amended claim 5 is not obvious over claim 1 of the '198 patent.

Accordingly, the withdrawal of the double patenting rejection is respectfully requested.

B. 35 U.S.C. §112, Second Paragraph

The Examiner also rejected claim 83 and 85-87 were rejected under 35 U.S.C. §112, second paragraph, for indefiniteness. Specifically, the Examiner pointed to the language in claim 83 reciting an "isolated polypeptide encoding a fusion polypeptide." Following the present amendment, claim 83 now recites an "isolated fusion polypeptide" in place of the original phrase. Thus, the indefiniteness rejection of claim 83 and its dependent claims is obviated.

III. Claim Objections

Claims 2, 3, and 7-18 were objected to for their dependency from rejected base claims. As discussed above, all claim rejections have now been properly addressed. Thus, the objection of these claims for depending from rejected base claims is moot.

Appl. No. 09/886,349
Amdt. dated May 12, 2005
Reply to Office Action of February 17, 2005

PATENT

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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Attachment (Exhibit 1: SEQ ID NO:2, SEQ ID NO:4, and SEQ ID NO:20, marked up to show correspondence)

CG:cg

60486599 v1

INFORMATION FOR SEQ ID NO:2:

(i) SEQUENCE CHARACTERISTICS:

- (A) LENGTH: 355 amino acids
(B) TYPE: amino acid
(C) STRANDEDNESS: single
(D) TOPOLOGY: linear

(xi) SEQUENCE DESCRIPTION: SEQ ID NO:2: MTB32A (Ra35FL)

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Met Ser Asn Ser Arg Arg Arg Ser Leu Arg Trp Ser Trp Leu Ser
1 5 10 15
Val Leu Ala Ala Val Gly Leu Gly Leu Ala Thr Ala Pro Ala Gln Ala
20 25 30
Ala Pro Pro Ala Leu Ser Gln Asp Arg Phe Ala Asp Phe Pro Ala Leu
35 40 45
Pro Leu Asp Pro Ser Ala Met Val Ala Gln Val Ala Pro Gln Val Val
50 55 60
Asn Ile Asn Thr Lys Leu Gly Tyr Asn Asn Ala Val Gly Ala Gly Thr
65 70 75 80
Gly Ile Val Ile Asp Pro Asn Gly Val Val Leu Thr Asn Asn His Val
85 90 95
Ile Ala Gly Ala Thr Asp Ile Asn Ala Phe Ser Val Gly Ser Gly Gln
100 105 110
Thr Tyr Gly Val Asp Val Val Gly Tyr Asp Arg Thr Gln Asp Val Ala
115 120 125
Val Leu Gln Leu Arg Gly Ala Gly Gly Leu Pro Ser Ala Ala Ile Gly
130 135 140
Gly Gly Val Ala Val Gly Glu Pro Val Val Ala Met Gly Asn Ser Gly
145 150 155 160
Gly Gln Gly Gly Thr Pro Arg Ala Val Pro Gly Arg Val Val Ala Leu
165 170 175
Gly Gln Thr Val Gln Ala Ser Asp Ser Leu Thr Gly Ala Glu Thr
180 185 190
Leu Asn Gly Leu Ile Gln Phe Asp Ala Ala Ile Gln Pro Gly Asp Ser
195 200 205
Gly Gly Pro Val Val Asn Gly Leu Gly Gln Val Val Gly Met Asn Thr
210 215 220
Ala Ala Ser Asp Asn Phe Gln Leu Ser Gln Gly Gly Gln Gly Phe Ala
225 230 235 240
Ile Pro Ile Gly Gln Ala Met Ala Ile Ala Gly Gln Ile Arg Ser Gly
245 250 255
Gly Gly Ser Pro Thr Val His Ile Gly Pro Thr Ala Phe Leu Gly Leu
260 265 270
Gly Val Val Asp Asn Asn Gly Asn Gly Ala Arg Val Gln Arg Val Val
275 280 285
Gly Ser Ala Pro Ala Ala Ser Leu Gly Ile Ser Thr Gly Asp Val Ile
290 295 300
Thr Ala Val Asp Gly Ala Pro Ile Asn Ser Ala Thr Ala Met Ala Asp
305 310 315 320
Ala Leu Asn Gly His His Pro Gly Asp Val Ile Ser Val Asn Trp Gln
325 330 335
Thr Lys Ser Gly Gly Thr Arg Thr Gly Asn Val Thr Leu Ala Glu Gly
340 345 350
Pro Pro Ala
355

402 in
No. 20
596 in No. 20

<213> Ra35 mature
<400> SEQ ID NO:4

402 in NO: 20

5 Met His His His His His His Ala Pro Pro Ala Leu Ser Gln Asp Arg
5 10 15

Phe Ala Asp Phe Pro Ala Leu Pro Leu Asp Pro Ser Ala Met Val Ala
20 25 30

10 Gln Val Gly Pro Gln Val Val Asn Ile Asn Thr Lys Leu Gly Tyr Asn
35 40 45

Asn Ala Val Gly Ala Gly Thr Gly Ile Val Ile Asp Pro Asn Gly Val
50 55 60

15 Val Leu Thr Asn Asn His Val Ile Ala Gly Ala Thr Asp Ile Asn Ala
65 70 75 80

20 Phe Ser Val Gly Ser Gly Gln Thr Tyr Gly Val Asp Val Val Gly Tyr
85 90 95

Asp Arg Thr Gln Asp Val Ala Val Leu Gln Leu Arg Gly Ala Gly Gly
100 105 110

25 Leu Pro Ser Ala Ala Ile Gly Gly Gly Val Ala Val Gly Glu Pro Val
115 120 125

Val Ala Met Gly Asn Ser Gly Gly Gln Gly Gly Thr Pro Arg Ala Val
130 135 140

30 Pro Gly Arg Val Val Ala Leu Gly Gln Thr Val Gln Ala Ser Asp Ser
145 150 155 160

35 Leu Thr Gly Ala Glu Glu Thr Leu Asn Gly Leu Ile Gln Phe Asp Ala
165 170 175

Ala Ile Gln Pro Gly Asp Ser Gly Gly Pro Val Val Asn Gly Leu Gly
180 185 190

40 Gln Val Val Gly Met Asn Thr Ala Ala Ser Asp Asn Phe Gln Leu Ser
195 200 205

Gln Gly Gly Gln Gly Phe Ala Ile Pro Ile Gly Gln Ala Met Ala Ile
210 215 220

45 Ala Gly Gln Ile Arg Ser Gly Gly Gly Ser Pro Thr Val His Ile Gly
225 230 235 240

50 Pro Thr Ala Phe Leu Gly Leu Gly Val Val Asp Asn Asn Gly Asn Gly
245 250 255

Ala Arg Val Gln Arg Val Val Gly Ser Ala Pro Ala Ala Ser Leu Gly
260 265 270

55 Ile Ser Thr Gly Asp Val Ile Thr Ala Val Asp Gly Ala Pro Ile Asn
275 280 285

Ser Ala Thr Ala Met Ala Asp Ala Leu Asn Gly His His Pro Gly Asp
290 295 300

60 Val Ile Ser Val Thr Trp Gln Thr Lys Ser Gly Gly Thr Arg Thr Gly
305 310 315 320

65 Asn Val Thr Leu Ala Glu Gly Pro Pro Ala
325 330

<210> SEQ ID NO:20

<211> 596

<212> PRT

<213> Artificial Sequence

<223> Description of Artificial Sequence:bi-fusion
protein TbH9-Ra35 (designated Mtb59f)

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60
65

His Met His His His His His His Met Val Asp Phe Gly Ala Leu Pro
1 5 10 15
Pro Glu Ile Asn Ser Ala Arg Met Tyr Ala Gly Pro Gly Ser Ala Ser
20 25 30
Leu Val Ala Ala Ala Gln Met Trp Asp Ser Val Ala Ser Asp Leu Phe
35 40 45
Ser Ala Ala Ser Ala Phe Gln Ser Val Val Trp Gly Leu Thr Val Gly
50 55 60
Ser Trp Ile Gly Ser Ser Ala Gly Leu Met Val Ala Ala Ala Ser Pro
65 70 75 80
Tyr Val Ala Trp Met Ser Val Thr Ala Gly Gln Ala Glu Leu Thr Ala
85 90 95
Ala Gln Val Arg Val Ala Ala Ala Ala Tyr Glu Thr Ala Tyr Gly Leu
100 105 110
Thr Val Pro Pro Pro Val Ile Ala Glu Asn Arg Ala Glu Leu Met Ile
115 120 125
Leu Ile Ala Thr Asn Leu Leu Gly Gln Asn Thr Pro Ala Ile Ala Val
130 135 140
Asn Glu Ala Glu Tyr Gly Glu Met Trp Ala Gln Asp Ala Ala Ala Met
145 150 155 160
Phe Gly Tyr Ala Ala Ala Thr Ala Thr Ala Thr Ala Thr Leu Leu Pro
165 170 175
Phe Glu Glu Ala Pro Glu Met Thr Ser Ala Gly Gly Leu Leu Glu Gln
180 185 190
Ala Ala Ala Val Glu Glu Ala Ser Asp Thr Ala Ala Ala Asn Gln Leu
195 200 205
Met Asn Asn Val Pro Gln Ala Leu Gln Gln Leu Ala Gln Pro Thr Gln
210 215 220
Gly Thr Thr Pro Ser Ser Lys Leu Gly Gly Leu Trp Lys Thr Val Ser
225 230 235 240
Pro His Arg Ser Pro Ile Ser Asn Met Val Ser Met Ala Asn Asn His
245 250 255
Met Ser Met Thr Asn Ser Gly Val Ser Met Thr Asn Thr Leu Ser Ser
260 265 270
Met Leu Lys Gly Phe Ala Pro Ala Ala Ala Ala Gln Ala Val Gln Thr
275 280 285
Ala Ala Gln Asn Gly Val Arg Ala Met Ser Ser Leu Gly Ser Ser Leu
290 295 300
Gly Ser Ser Gly Leu Gly Gly Gly Val Ala Ala Asn Leu Gly Arg Ala
305 310 315 320
Ala Ser Val Gly Ser Leu Ser Val Pro Gln Ala Trp Ala Ala Ala Asn
325 330 335

Gln Ala Val Thr Pro Ala Ala Arg Ala Leu Pro Leu Thr Ser Leu Thr
 340 345 350
 5 Ser Ala Ala Glu Arg Gly Pro Gly Gln Met Leu Gly Gly Leu Pro Val
 355 360 365
 Gly Gln Met Gly Ala Arg Ala Gly Gly Gly Leu Ser Gly Val Leu Arg
 370 375 380
 10 Val Pro Pro Arg Pro Tyr Val Met Pro His Ser Pro Ala Ala Gly Asp
 385 390 395
 33 in NO: 2, 8 in NO: 4 NO: 14
 15 Ile Ala Pro Pro Ala Leu Ser Gln Asp Arg Phe Ala Asp Phe Pro Ala
 405 410 415
 Leu Pro Leu Asp Pro Ser Ala Met Val Ala Gln Val Gly Pro Gln Val
 420 425 430
 20 Val Asn Ile Asn Thr Lys Leu Gly Tyr Asn Asn Ala Val Gly Ala Gly
 435 440 445
 Thr Gly Ile Val Ile Asp Pro Asn Gly Val Val Leu Thr Asn Asn His
 450 455 460
 25 Val Ile Ala Gly Ala Thr Asp Ile Asn Ala Phe Ser Val Gly Ser Gly
 465 470 475 480
 30 Gln Thr Tyr Gly Val Asp Val Val Gly Tyr Asp Arg Thr Gln Asp Val
 485 490 495
 Ala Val Leu Gln Leu Arg Gly Ala Gly Gly Leu Pro Ser Ala Ala Ile
 500 505 510
 35 Gly Gly Gly Val Ala Val Gly Glu Pro Val Val Ala Met Gly Asn Ser
 515 520 525
 Gly Gly Gln Gly Gly Thr Pro Arg Ala Val Pro Gly Arg Val Val Ala
 530 535 540
 40 Leu Gly Gln Thr Val Gln Ala Ser Asp Ser Leu Thr Gly Ala Glu Glu
 545 550 555 560
 45 Thr Leu Asn Gly Leu Ile Gln Phe Asp Ala Ala Ile Gln Pro Gly Asp
 565 570 575
 Ser Gly Gly Pro Val Val Asn Gly Leu Gly Gln Val Val Gly Met Asn
 580 585 590
 50 Thr Ala Ala Ser
 595

227 in NO: 2
 202 in NO: 4